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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,796	12/14/2001	Erhard Mueller	24857	1639
20529	7590	01/27/2006	EXAMINER	
NATH & ASSOCIATES 112 South West Street Alexandria, VA 22314			GRAY, JILL M	
			ART UNIT	PAPER NUMBER

1774

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/014,796	MUELLER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jill M. Gray	1774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 27,29,30 and 34-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27,29,30 and 34-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 27, 29-30, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erneta et al, 5,854,383 (Erneta) in view of Oberhoffner et al, 6,048,947 (Oberhoffner), for reasons of record.

Erneta teaches absorbable copolymers of aliphatic polyester comprising trimethylene carbonate, e-caprolactone and glycolide. See column 1, lines 6-10. The amount of glycolide typically consist of about 10 mole percent to about 80 mole percent, and the mole percentages of trimethylene carbonate to e-caprolactone to glycolide are respectively about 2 to about 40; 2 to about 40 and about 2 to about 35. See column 4, lines 13-21. The polymers have a molecular weight within applicants' range as set forth in claim 30 and can be used as a coating for a suture material comprising one or more filaments. See column 4, lines 1-5 and column 5, lines 14-42. Erneta does not teach the weight percent of his monomers or the glass transition temperature and random polymerization. However, his teaching of 10 mole percent of glycolide would have provided a suggestion to the skilled artisan that this component could be present in lowered amounts with a reasonable expectation of success of forming an absorbable polymer. Oberhoffner teaches a triblock polymer comprising a biodegradable hard

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segment and a biodegradable soft segment comprising a random terpolymer. The biodegradable soft segment is formed from trimethylene carbonate, ε-caprolactone and glycolide, wherein the trimethylene carbonate can be present in a percentage of 5 to 70 wt%, ε-caprolactone in a percentage of 5 to 70 wt% and glycolide in a percentage of 10 to 70 wt%, wherein the trimethylene carbonate and ε-caprolactone can be present in a weight ratio of 70:30 and 30:70. See column 2, lines 36-55 and claim 1. Also, Oberhoffner teaches that his soft segment is completely amorphous and has a glass transition temperature in the range of  $-30^{\circ}\text{C}$  and  $+10^{\circ}\text{C}$ . See column 3, lines 36-40 and line 55. Oberhoffner does not teach his soft segment by itself or its' use as a coating material.

It is the examiner's position that the skilled artisan is expected and presumed to know something about the art other than what a reference literally teaches. In the present case, one of ordinary skill would have knowledge of bioresorbable polymers, copolymers and terpolymers, in particular, terpolymers of glycolide, ε-caprolactone and trimethylene carbonate. The teachings of Erneta and Oberhoffner provide evidence of this. Though Oberhoffner teaches his terpolymer as a segment of a triblock polymer, this does not preclude the expectation that his terpolymer can stand alone. Furthermore, the addition of monomers to preexisting copolymers is an obvious variant to one of ordinary skill in this art. As such, the skilled artisan in possession of the teachings of Oberhoffner would immediately envisage the utility of the soft segment separate from the triblock.

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Erneta is silent as to the weight percent of his components and ratio of e-caprolactone and trimethylene carbonate. It is the examiner's position that at the time of the invention, one of ordinary skill in the art in possession of teachings of Erneta would have been reasonably motivated to modify the composition of Erneta by using the weight ratios taught by Oberhoffner with the reasonable expectation of obtaining a coating that is completely amorphous having enhanced in vivo degradability. Furthermore, bioresorbable terpolymers of e-caprolactone, trimethylene carbonate, and glycolide and coating compositions formed therefrom are known. Accordingly, it is the examiner's position that since the results sought and the ingredients used were known, it was within the expected skills of one having ordinary skill in this art to arrive at the optimum proportions of those ingredients. Hence, in view of the prior art teachings of Erneta and Oberhoffner, the amounts of e-caprolactone, trimethylene carbonate and glycolide would have been obvious to one having ordinary skill in the art at the time the invention as claimed in claims 27 and 29 was made.

Therefore, the combined teachings of Erneta and Oberhoffner would have rendered obvious the invention as claimed in present claims 27 and 29-30.

3. Claims 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Erneta et al, 5,854,383 (Erneta) in view of Oberhoffner et al, 6,048,947 (Oberhoffner), each as applied above to claims 27 and 29-30, further in view of Bezwada et al, 5,371,176, for reasons of record.

Erneta and Oberhoffner are as set forth above but do not teach the inclusion of a plasticizer or the coating formed from mixture of the bioresorbable polymer with fatty

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acid salts or amount of add on. Bezwada is as set forth in prior Office Actions and teaches a polymer comprising caprolactone, trimethylene carbonate and glycolide, wherein his polymer can contain fatty acid salts as set forth by applicants in claim 34 and a plasticizer in an amount ranging from 0.5 to about 30 part by weight, per claim 35 and that the coating can be applied to the surface of the suture in an amount ranging from about 0.5 to about 30 percent of the weight of the coated suture. The teachings of Bezwada would have provided direction to the skilled artisan at the time the invention was made to modify the composition of Erneta by including a plasticizer in an amount within applicants' range in order to enhance the performance of the polymer.

Furthermore, the teachings of Bezwada would have provided a suggestion and motivation to the skilled artisan to coat the composition onto a suture material such that the coating represents 0.5 to about 30 wt% of the total weight of the coated suture material, as required by claim 36 to result in a coated suture that is slippery and easy to manipulate without increasing the risk of the coating flaking off.

Therefore, the combined teachings of Erneta, Oberhoffner and Bezwada would have rendered obvious the invention as claimed in present claims 34-36.

### ***Response to Arguments***

4. Applicant's arguments filed October 28, 2005 have been fully considered but they are not persuasive.

Applicants argue that both Erneta and Oberhoffner disclose segmented triblockterpolymers that are each prepared in a multi-step reaction of trimethylene carbonate, caprolactone and glycolide, whereas the terpolymer formed in the present

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application is formed by the simultaneous reaction of the monomers of glycolide, ε-caprolactone and trimethylene carbonate as a random polymer.

In this regard, the claims are not limited to a simultaneous reaction of monomers.

Applicants argue that the terpolymer of Erneta results in a glycolide amount between a minimum of 20% and a maximum of 96%, whereas the present claims require a glycolide concentration of 10-20%.

In this concern, it is the examiner's position that an amount of glycolide of 20% as taught by Erneta overlaps and therefore renders obvious the range contemplated by applicants. Accordingly, the teachings of Erneta would obviate the claimed critical range.

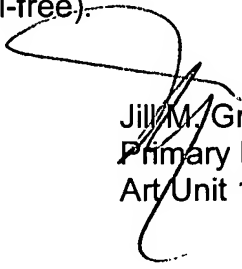
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jill M. Gray whose telephone number is 571-272-1524. The examiner can normally be reached on M-Th and alternate Fridays 10:30-7:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on 571-272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jill M. Gray  
Primary Examiner  
Art Unit 1774

jmg